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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,413	08/07/1998	HANS JOSEF STAUSS	RPMS102	9623

7590 12/11/2001  
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EXAMINER
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EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/101,413**

Applicant(s)  
**Stauss, H.**

Examiner  
**G. R. Ewoldt**

Art Unit  
**1644**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Oct 2, 2001

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-18 and 25-29 is/are pending in the application.

4a) Of the above, claim(s) 9-13 and 27 is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-8, 14-18, 25, 26, 28, and 29 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some\* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 1-8, 14-18, 25-26, and 28-29 are pending and being acted upon.

2. In view of Applicant's amendment and response, filed 10/02/01, only the following rejections remain.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8, 14-18, 25-26, and 28-29 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record, as set forth in Paper No. 22, mailed 6/28/01.

Applicant's arguments, filed 10/02/01, have been fully considered but have not been found persuasive. Applicant argues that because the specification provides examples of mutant polypeptides the term is adequately described. Applicant further argues that a polypeptide derived from, or produced as a result of a mechanism induced by a tumor, bacteria, or virus would be abnormal. However, it is the Examiner's position that neither the disclosed examples nor Applicant's newly asserted definition adequately delineate the metes and bounds of the claimed invention.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-8, 14-18, 25-26, and 28-29 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed, for the reasons of record, as set forth in Paper No. 22, mailed 6/28/01.

Applicant's arguments, filed 10/02/01, have been fully considered but have not been found persuasive. First note that Applicant has misrepresented the previous Office action with the statement that "The Examiner states that there is no support for the phrase, 'the cells to be killed.'" A careful review of the previous Office action will show that the Examiner actually wrote "no specific passages in the specification are offered in support of the new limitations." Applicant argues that the disclosures found on page 58 (in view of page 47), page 51, page 42, as well as Example 3 and Figure 7, fully support the rejected claims. It is the Examiner's position that said passages, figures, and examples may disclose, or function through, concepts that fall within the scope of the amended claims, however, said passages, figures, and examples are insufficient support for claims drawn to the entire genus of methods encompassed by the amended claims.

7. Claim 5 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record, as set forth in Paper No. 22, mailed 6/28/01.

Applicant's arguments, filed 10/02/01, have been fully considered but have not been found persuasive. Note that "abnormal molecule" has been deleted from the claims. Thus, the rejections based on the recitation of "abnormal molecule" have been withdrawn. Applicant has not specifically argued the rejection of claims reciting "mutant polypeptide". Further note that Applicant is simply scientifically incorrect in the assertion that one cannot have a cell in a diseased state without an abnormal antigen or have an abnormal antigen without a cell in a diseased state ("Without one you cannot have the other.").

8. The following are New Grounds for Rejection, necessitated by Applicant's amendment filed 10/02/01.

9. Claims 1-8, 14-18, 25-26, and 28-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, in claim 1 it is unclear what the term "abnormal antigen" means, as the term has not been defined in the specification.

It is noted that Applicant's arguments, filed 10/02/01, have included arguments supporting the recitation of the term "abnormal antigen," however, these arguments have not been found persuasive. Applicant argues that "An abnormal antigen is defined, for example, on page 7, lines 24-28, in view of lines 3-22 on the same page." However, the term "abnormal antigen" has not been found on the cited page. Further, it is unclear to the Examiner how a term can be defined "for example," as "for example" implies that the disclosed example is not limiting and thus not defining.

10. Claims 1-8, 14-18, 25-26, and 28-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

There is insufficient written description to show that Applicant was in possession of an "abnormal antigen". The specification fails to specifically define the term. Additionally, the specification fails to disclose any specific examples of an "abnormal antigen". As the term would potentially encompass an essentially unlimited genus, one of skill in the art would conclude that the specification fails to disclose a representative number of species to describe the claimed genus. See *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Serial No. 09/101,413  
Art Unit 1644

5

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

G.R. Ewoldt, Ph.D.  
Patent Examiner  
Technology Center 1600  
December 10, 2001



Patrick J. Nolan, Ph.D.  
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